GOVERNMENT OF THE REPUBLIC OF ARMENIA

DECISION

No 162-N of 28 February 2019

ON ESTABLISHING THE PROCEDURE FOR STATE REGISTRATION, RE-REGISTRATION OF MEDICINE IN THE REPUBLIC OF ARMENIA, EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE, AS WELL AS FOR REFUSING REGISTRATION, RE-REGISTRATION, EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE, SUSPENSION, REVOCATION OF REGISTRATION, THAT FOR EXPERT-EXAMINATIONS CONDUCTED FOR THESE PURPOSES, AS WELL AS THE PROCEDURE FOR SUBMITTING POST-REGISTRATION MODIFICATIONS AND EXPERT-EXAMINATION, THE LIST OF NECESSARY DOCUMENTS, THE LIST OF MODIFICATIONS CONCERNING THE REGISTERED MEDICINES, WHERE NO NEW REGISTRATION IS REQUIRED, THE PROCEDURE FOR RECOGNITION OF PROFESSIONAL MONITORING AND MONITORING REPORTS OF COMPETENT AUTHORITIES OF OTHER COUNTRIES, AND ON REPEALING DECISION OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA NO 347 OF 25 APRIL 2001

Based on parts 2, 10, 17, 19, 20 and 22 of Article 16 of the Law of the Republic of Armenia "On medicines", the Government of the Republic of Armenia shall hereby decide:

1. To approve:

   (1) the Procedure for state registration, re-registration of medicine in the Republic of Armenia, extending the validity period of the certificate, as well

as for refusing registration, re-registration, extending the validity period of the certificate, suspension and revocation of registration, in accordance with Annex No 1;

(2) the Procedure for expert-examination conducted for the purpose of state registration, re-registration of medicine, extending the validity period of the certificate, as well as for submitting post-registration amendments and expert-examination, in accordance with Annex No 2;

(3) the List of documents required for expert-examination, conducted for the purpose of state registration, re-registration of medicine, extending the validity period of the certificate, as well as for submitting post-registration modifications and expert-examination, in accordance with Annex No 3;

(4) the List of modifications concerning the registered medicines, where no new registration is required, in accordance with Annex No 4;

(5) the Procedure for recognition of professional monitoring and monitoring reports of competent authorities of other countries, in accordance with Annex No 5.

2. To repeal Decision of the Government of the Republic of Armenia No 347 of 25 April 2001 "On approving the procedure for state registration of medicine in the Republic of Armenia and the amount of expert-examination fees for state registration of medicine".

3. This Decision shall enter into force on the tenth day following the day of its official promulgation.

Prime Minister
of the Republic of Armenia N. Pashinyan

7 March, 2019

Yerevan

Annex No 1

to Decision of the Government
of the Republic of Armenia
No 162-N of 28 February 2019

PROCEDURE

FOR STATE REGISTRATION, RE-REGISTRATION OF MEDICINE IN THE REPUBLIC OF ARMENIA, EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE, AS WELL AS FOR REFUSING REGISTRATION, RE-REGISTRATION, EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE, SUSPENSION AND REVOCATION OF REGISTRATION

1. GENERAL PROVISIONS

1. This Procedure shall regulate the relations with respect to the state registration, re-registration of medicine in the Republic of Armenia, extending the validity period of the certificate, as well as for refusing registration, re-registration of medicine and extending the validity period of the certificate, suspension and revocation of registration, in accordance with Annex No 1. Registration of medicines for human use shall be carried out in accordance with the registration and expert-examination rules approved by Decision of the Council of the Eurasian Economic Commission No 78 of 3 November 2016. Registration of veterinary medicines shall also be carried out in accordance with the rules for circulation of veterinary medicines approved by Decision of the Council of the Eurasian Economic Commission No 1 of 21 January 2022.

(point 1 edited by No 2143-N of 23 December 2021, supplemented by No 1873-N of 28 November 2024)

2. The Republic of Armenia shall permit the manufacturing, import, distribution, release, sales and use of the medicines registered in the Republic of Armenia, except for the cases prescribed by part 23 of Article 16 and part 6 of Article 21 of the Law of the Republic of Armenia "On medicine".

3. Pursuant to part 2 of Article 16 of the Law of the Republic of Armenia "On medicine", the requirements of this Procedure shall not apply to the legal relations with respect to the state registration, refusing, suspending and revoking the registration of veterinary vaccines, serums and diagnostic agents.

4. The medicines for human use registered in the Republic of Armenia before 1 July 2021 may be re-registered or modifications can be made to the registration documents thereof, in accordance with this Procedure, within the terms and under the conditions established by Decision of the Council of the Eurasian Economic Commission No 78 of 3 November 2016.

   (point 4 edited by No 2143-N of 23 December 2021, amended by No 1873-N of 28 November 2024)

5. Registration, re-registration of medicine, extending the validity period of the certificate, as well as the refusal, suspension, and revocation of registration shall be carried out by the Ministry of Healthcare of the Republic of Armenia (hereinafter referred to as "the Authorized Body") based on the expert-examination opinion issued as a result of the expert-examination conducted in accordance with Annex No 2 to this Decision.

6. Pursuant to part 21 of Article 16 of the Law of the Republic of Armenia "On medicine", a state duty shall be levied for the registration, re-registration, re-issuance of the certificate and extension of the validity period thereof in the manner and in the amount prescribed by the Law of the Republic of Armenia "On state duty".

7. Expert-examinations for the purpose of registration, re-registration of medicines, extending the validity period of the certificate, revocation of registration, re-registration, extending the validity period of the certificate, suspension of registration of medicine, as well as for post-registration modifications shall be conducted by an expert organisation (hereinafter referred to as "the Organisation") established by a decision of the Government of the Republic of Armenia.

8. The decisions on refusing the registration, re-registration, extension of the validity period of the certificate of the medicine, revoking, suspending the registration of the medicine may be appealed against as prescribed by the Law of the Republic of Armenia "On fundamentals of administrative action and administrative proceedings" or through judicial procedure.

2. STATE REGISTRATION OF MEDICINES

9. Pursuant to part 4 of Article 16 of the Law of the Republic of Armenia "On medicine", the registration of medicine shall be based on scientifically justified criteria for safety, efficiency and quality of products adopted as prescribed by the legislation of the Republic of Armenia and the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (hereinafter referred to as "ICH").

10. Pursuant to part 3 of Article 16 of the Law of the Republic of Armenia "On medicine", medicines shall be registered in the Republic of Armenia through general and simplified procedure, in case of availability of a positive expert-examination opinion.

11. Simplified procedure for registration of medicine shall be applied to the medicines registered (undergone expert-examination) in a member state of the ICH or pre-qualified by the World Health Organisation (hereinafter referred to

as “the WHO”) (hereinafter referred to as “the Referring Competent Authority”), within the terms specified in point 20 of this Procedure.

(point 11 supplemented by No 1873-N of 28 November 2024)

12. In all other cases, the general procedure for registration of medicine shall apply, within the terms specified in point 19 of this Procedure.

13. For the purpose of registration, the person defined in part 9 of Article 16 of the Law of the Republic of Armenia "On medicine" may act as an applicant and (or) submit documents of registration.

14. For the purpose of registration, re-registration and post-registration modifications, the applicant shall submit a request and the necessary documents to the Organisation, in accordance with the list approved by Annex No 3 to this Decision, the laboratory expert-examination samples, standards, specific reagents (hereinafter referred to as “Materials”). The documents shall be submitted in person and (or) by e-mail and (or) through an electronic system and (or) by postal delivery. Data on the request and the list of documents shall be available on the website www.moh.am, differentiating the lists of documents for registration of medicines of human use and veterinary medicines.

15. For the purpose of extending the validity period of the certificate, the holder of the certificate of registration shall submit an application in the forms specified in point 14, indicating the name, dosage, pharmaceutical form, number of the previous certificate of medicine and necessary documents, in accordance with Annex No 3 to this Decision.

16. The registration of the request and application in the Organisation shall be ensured during working days and hours. The documents submitted on non-working days and hours shall be considered to have been submitted on the following working day.

17. The fact that the application or request has been registered with the Organisation shall be confirmed within the same day by sending a return e-mail to the applicant's e-mail address. Following the registration of requests and applications, the Organisation shall inform the Authorised Body.

18. The Organisation shall ensure the confidentiality of the data in the documents submitted for registration that are considered information protected by law of the Republic of Armenia and are not subject to publication.

19. The total maximum term for registration of medicine shall be 150 calendar days which includes the term of the expert-examination for the purpose of registration, the maximum duration of which shall be 140 calendar days.

20. The maximum term of registration through simplified procedure shall be 31 calendar days which includes the term of the expert-examination for the purpose of registration, the maximum duration of which shall be 21 calendar days.

21. Where the applicant makes supplements to the documents during the expert-examination, the expert-examination shall be extended for 10 calendar days, which the applicant shall be notified about within 2 working days following the receipt of the documents, by postal delivery or via e-mail.

22. The period for submitting the materials, data, documents requested from the applicant during the expert-examination shall not be included in the total period for conducting the expert-examination.

23. The applicant shall have the right to refuse the registration at any stage of the expert-examination, in the manner prescribed by part 16 of Article 16 of the Law "On medicine".

(point 23 edited by No 1873-N of 28 November 2024)

24. Pursuant to part 5 of Article 16 of the Law of the Republic of Armenia "On medicine", each name, composition, dosage, pharmaceutical form, application

form, release form (form of presentation with a certain number of units included in a package), new indication, manufacturer (including those conducting each manufacturing process), holder of the certificate of registration of medicine shall be subject to registration.

(point 24 supplemented by No 1873-N of 28 November 2024)

25. The primary and (or) outer packaging, label, make (including in the form of colourful illustrations) of the medicine, instruction for medical use (general description of the medicine), instruction for use (leaflet) and quality specifications or the normative document of quality shall be approved during the registration.

(point 25 supplemented by No 1873-N of 28 November 2024)

26. Pursuant to part 7 of Article 16 of the Law of the Republic of Armenia "On medicine", the quality of the product, active ingredients and excipients, the container and sealing materials subject to registration in the Republic of Armenia must comply with the requirements of pharmacopoeias included in the list approved by the Government of the Republic of Armenia, in accordance with point 33 of part 1 of Article 3 of the Law of the Republic of Armenia "On medicine". The studies of quality, safety and efficiency of medicines registered in the Republic of Armenia must be conducted in compliance with the ICH and the WHO guidelines, unless otherwise provided for by international treaties and other international documents.

27. During the registration, the fact of whether or not the medicine falls under the groups of medicines sold on prescription or with no prescription and (or) controlled medicine shall be determined in accordance with part 24 of Article 16 of the Law of the Republic of Armenia “On medicine”.

28. Based on part 8 of Article 16 of the Law of the Republica of Armenia “On medicine”, the registration of medicines containing different medical substances

but having the same or confusingly similar names shall be prohibited. The requirements to the names shall be established by the Authorised Body.

29. The Organisation shall submit the expert-examination opinion conducted in accordance with the Procedure provided for by Annex No 2 to this Decision to the Authorised Body on the working day following the end of the expert-examination.

30. The Authorised Body shall issue an order on registration of the medicine within 3 working days upon receipt of the positive expert-examination opinion.

31. The term for registration of the medicine shall be five years, which is calculated from the date of entry into force of the order of the Authorised Body on registration of the medicine. The Authorised Body shall — within 5 working days — issue a certificate of registration in the form approved by the Authorised Body to the applicant, in case of availability of a document confirming the payment of the state duty. The primary and (or) outer packaging of the medicine, label, instruction for medical use in Armenian (general description of the medicine) and the instruction for use (leaflet) thereof, which serve as a basis for identification and (or) official information of medicines in all the phases of circulation of medicines in the Republic of Armenia, shall be provided to the holder of the certificate of registration. The certificate of registration and accompanying documents shall be provided to the applicant via e-mail.

(point 31 supplemented, edited by No 1873-N of 28 November 2024)

32. Data on the registered medicine, as well as the primary and (or) outer packaging of the medicine, label, instruction for medical use in Armenian (general description of the medicine) and the instruction for use (leaflet) thereof shall be included in the register, in accordance with the procedure approved by the Authorised Body. The Organisation shall ensure the publicity of the register, the primary and (or) outer packaging of the registered medicine, label, instruction

for medical use in Armenian (general description of the medicine) and the instruction for use (leaflet) thereof and post on the official website. The same information should be available also on the website www.moh.am.

33. The order on registration of medicine shall be published as prescribed by law.

34. Pursuant to part 22 of Article 16 of the Law of the Republic of Armenia "On medicine", the holder of the certificate of registration of the medicine shall be responsible, as prescribed by law, for the safety, efficacy, quality of the registered product, and shall be obliged to promptly notify the Authorised Body in writing of each new data thereon and (or) modification thereof being identified and (or) made in the post-registration period, including the data of the competent body of any country on prohibition or restriction on the use of the product. These modifications shall be submitted and be subjected to expert-examination in accordance with Annex No 2. The modifications shall be considered adopted from the date of entry into force of the order of the Authorised Body thereon, based on which they shall also be included in the register.

3. RE-REGISTRATION OF THE MEDICINE AND EXTENSION OF THE VALIDITY PERIOD OF REGISTRATION CERTIFICATE

35. Pursuant to part 19 of Article 16 of the Law of the Republic of Armenia "On medicine", after the expiry of the validity period of registration, re-registration may be made for a period of five years.

36. Re-registration may be carried out based on a written request of the holder of the certificate of registration, which shall be submitted to the Organisation before the expiry of the validity period of the previous certificate of registration, but not earlier than 210 calendar days, in person and (or) by e-mail and (or) through an electronic system and (or) by postal delivery.

(point 36 supplemented by No 2143-N of 23 December 2021)

37. When re-registering medicine, the safety, efficiency, and quality of the product shall be re-assessed based on the results of post-registration professional monitoring of safety.

38. The maximum duration of re-registration process of the medicine shall be 120 calendar days which includes the term of the expert examination, i.e. 110 calendar days.

(point 38 edited by No 1873-N of 28 November 2024)

39. The Organisation shall submit the expert-examination opinion conducted in accordance with the Procedure provided for by Annex No 2 to this Decision to the Authorised Body on the working day following the end of the expert-examination.

40. The Authorised Body shall issue an order on re-registration of the medicine within 3 working days upon receipt of the positive expert-examination opinion and the register shall be revised, the data on the re-registration being added therein.

41. The order on re-registration of medicine shall be published as prescribed by law.

42. Within 5 working days from the date of entry into force of the order of the Authorised Body on the re-registration of medicine, the applicant shall be issued a certificate of re-registration for a period of 5 years, starting from the day following the expiry of the validity period of previous certificate.

(point 42 amended by No 2143-N of 23 December 2021, No 1873-N of 28 November 2024)

43. Following the expiry of the term of re-registration, the validity period of the certificate of registration may be extended every five years, based on the results of post-registration professional monitoring of safety by the Authorised Body.

44. Following the expiry of the term of re-registration, the validity period of the certificate of registration shall be extended in case of availability of the

application by the holder of the certificate of registration, which shall be submitted to the Organisation before the expiry of the validity period of the previous certificate of registration, but not earlier than 210 calendar days, in person and (or) by e-mail and (or) through an electronic system and (or) by postal delivery.

(point 44 supplemented by No 2143-N of 23 December 2021)

45. The maximum duration of extension process of the validity period of the certificate of registration of the medicine shall be 30 calendar days which includes the term of the expert examination, i.e. 20 calendar days.

(point 45 edited by No 1873-N of 28 November 2024)

46. The Organisation shall submit the expert-examination opinion conducted in accordance with the Procedure provided for by Annex No 2 to this Decision to the Authorised Body on the working day following the end of the expert-examination.

47. The Authorised Body shall issue an order on extending the validity period of the certificate of registration of the medicine within 3 working days upon receipt of the positive expert opinion and the register shall be revised, the data on extending the validity period of the certificate being added therein.

48. The order on extending the validity period of the certificate of registration of medicine shall be published as prescribed by law.

49. Within 5 working days from the date of entry into force of the order of the Minister on extending the validity period of the certificate of registration of medicine, the applicant shall be issued a new certificate for a period of 5 years, starting from the day following the expiry of the validity period of previous certificate.

(point 49 amended by No 2143-N of 23 December 2021, No 1873-N of 28 November 2024)

50. The new certificate of registration shall be issued to the applicant via e-mail.

(point 50 amended by No 1873-N of 28 November 2024)

4. REFUSING REGISTRATION, RE-REGISTRATION OF MEDICINE, EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE, REVOCATION OF REGISTRATION, SUSPENSION OF REGISTRATION OF MEDICINE

51. The registration, re-registration, extension of the validity period of the certificate of the medicine shall be rejected in the cases prescribed by part 27 of Article 16 of the Law of the Republic of Armenia "On medicine".

52. The order on refusing registration, re-registration of medicine, extending the validity period of the certificate shall be adopted within 5 working days upon receipt of the the expert opinion.

53. Within 2 working days from the moment of adopting the order of the Minister on refusing, it shall be sent to the applicant via e-mail.

(point 53 amended by No 1873-N of 28 November 2024)

54. The request submitted by the same applicant for the same medicine, the registration, re-registration, or extending the validity period of the certificate whereof has been refused, shall not be processed through the process established by this Procedure, unless the grounds for refusal have been eliminated.

55. The registration, re-registration, extension of the validity period of the certificate of the medicine shall be revoked in the cases prescribed by part 29 of Article 16 of the Law of the Republic of Armenia "On medicine".

56. The order on revocation of the registration, re-registration of medicine, or extending the validity period of the certificate of registration shall be adopted within a maximum of 3 working days upon receipt of the expert opinion.

57. The order on revocation of the registration, re-registration of medicine, extending the validity period of the certificate shall — within one working day from the moment of its entry into force — be sent to the applicant, the Health and Labour Inspection Body of the Republic of Armenia (hereinafter referred to as “the Inspection Body”), and the entities of medicine circulation via e-mail.

(point 57 amended by No 1873-N of 28 November 2024)

58. From the moment of entry into force of the order on revocation of registration, re-registration, extending the validity period of the certificate, the medicine shall be removed from the register and the medicine shall be recalled, as prescribed by the decision of the Government of the Republic of Armenia.

59. Pursuant to part 30 of Article 16 of the Law of the Republic of Armenia “On medicine”, in case of revoking the registration of the medicine, the manufacture, import, distribution, release, sales and use of the medicine shall be prohibited.

60. The registration of the medicine shall be suspended in the cases prescribed by part 31 of Article 16 of the Law of the Republic of Armenia "On medicine".

61. In the cases provided for by point 1 of part 31 of Article 16 of the Law of the Republic of Armenia "On medicine", the registration of the medicine shall be suspended for a term offered by the holder of the certificate of registration and in the cases provided for by points 2-4, until the violations or inconsistencies are eliminated.

62. The order on suspending the registration of medicine shall be adopted within one working day upon receipt of the expert-examination opinion, indicating the term of suspension.

63. The order on suspending the registration of medicine shall — within one working day from the moment of its adoption — be sent to the applicant, the Inspection Body, and the entities of medicine circulation via e-mail, and a relevant note shall be made in the register of medicine.

(point 63 amended by No 1873-N of 28 November 2024)

64. The registration of suspended medicine shall be restored based on the application of the holder of the certificate of registration from the day following the expiry of the term of suspension. In other cases, the suspension of registration of medicine shall be restored in case of availability of a positive expert opinion.

65. Pursuant to part 32 of Article 16 of the Law of the Republic of Armenia “On medicine”, in case of suspending the registration of the medicine, the manufacture, import, distribution, release, sales and use of the medicine shall be temporarily prohibited.

66. Where the registration has been suspended in the cases prescribed by part 31 of Article 16 of the Law of the Republic of Armenia "On medicine" due to considerations regarding quality, safety and efficiency, which directly affected the manufactured and imported batches, the medicine shall be recalled following termination of circulation, as prescribed by the decision of the Government of the Republic of Armenia.

(Annex edited, supplemented, amended by No 2143-N of 23 December 2021, No 1873-N of 28 November 2024)

Prime Minister
of the Republic of Armenia N. Pashinyan

Annex No 2

to Decision of the Government
of the Republic of Armenia
No 162-N of 28 February 2019

PROCEDURE

FOR EXPERT-EXAMINATION CONDUCTED FOR THE PURPOSE OF STATE REGISTRATION, RE-REGISTRATION OF MEDICINE, EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE, AS WELL AS FOR SUBMITTING POST-REGISTRATION MODIFICATIONS AND EXPERT-EXAMINATION

1. GENERAL PROVISIONS

1. This Procedure shall regulate the legal relations with respect to the expert-examination conducted for the purpose of state registration, re-registration of medicine in the Republic of Armenia, extending the validity period of the certificate, the expert-examination conducted for the purpose of revocation of registration, re-registration, extending the validity period of the certificate, and that of suspending the registration of medicine, as well as the expert-examination conducted for post-registration modifications.

2. Pursuant to part 14 of Article 16 of the Law of the Republic of Armenia "On medicine", the expert conducting an expert-examination for the purpose of registration shall be obliged to sign a declaration of conflict of interests and confidentiality in the form prescribed by the Authorised Body.

3. The documents required for the expert-examination may be submitted via electronic or other material medium.

   (point 3 amended by No 1873-N of 28 November 2024)

4. The documents and colour diagrams of medicine packages (including post-registration modifications) may be submitted for expert-examination in Armenian and (or) Russian and (or) English.

5. The laboratory expert-examination samples, standards, specific reagents (hereinafter referred to as "Materials") shall be submitted only for medicines registered in Armenia for the first time and in cases where quality-related modifications have been made to the specifications or the normative document of

quality, except for the medicines registered in the member states of the ICH and those prequalified by the WHO. Materials shall be submitted in quantities sufficient to perform three analyses in accordance with the specification or the normative document of quality, as notified by the Organisation. The remaining shelf-life of the submitted materials must be at least six months, except for the cases where the shelf-life thereof is less than six months.

(point 5 amended, supplemented by No 1873-N of 28 November 2024)

6. Material shall not be required in cases where ensuring the availability thereof is associated with certain difficulties, in particular, medicines containing narcotic drugs and psychotropic substances, or in cases where it is impossible to ensure special conditions for transportation or storage. In the above-mentioned cases, laboratory examination shall be conducted upon first import, for which an additional sample shall be submitted. Where different dosage (dosages), manufacturing site(s), and application, packaging, and release form(s) of the same medicine are submitted in one request, only one medicine shall be subjected to laboratory examination, selected at random.

(point 6 supplemented by No 1873-N of 28 November 2024)

7. In case there is an item of medical significance in the package of the medicine, the documents of registration must contain data and a conclusion issued by the competent authority on its safety, quality and efficiency, as well as its impact on the clinical characteristics of the medicine, or a certificate of registration.

8. The applicant shall be liable for the authenticity of the submitted documents, the reliability, up-to-dateness, and compliance of the information with the requirements of the legislation. In case of any deviation, appropriate justification must be presented for evaluation during the expert-examination.

9. The expert-examination shall start after the Organisation sends a notification of receipt of the request, in case of availability of documents certifying the fact of payment of the state duty established for the expert-examination.

(point 9 edited by No 1873-N of 28 November 2024)

10. In case of submitting documents simultaneously in one request (application) for the purpose of harmonising the first pharmaceutical form, the first and each subsequent dosage (dosages), the manufacturing site (s) and the application, packaging and release form (s) of the medicine, except for the subsequent pharmaceutical form, registration (re-registration, extending the validity period of the certificate), and the package of a registered medicine, a document certifying the fact of payment of the state duty established for the conduct of one expert-examination shall be submitted for the expert-examination.

(point 10 edited by No 1873-N of 28 November 2024)

11. When submitting the documents of registration (re-registration, extending the validity period of the certificate) of or post-registration modifications to each subsequent pharmaceutical form, new dosage, manufacturing site, indication, application, packaging and release forms of a registered medicine for expert-examination, the documents certifying the fact of payment of the state duty shall be submitted, according to the rates established for each case.

(point 11 edited by No 1873-N of 28 November 2024)

12. The expert-examination of registration, re-registration, extending the validity period of the certificate of, and post-registration modifications to low-demand but vitally important medicines, including "orphan" medicines, may be conducted within the framework of a state order issued by the Authorised Body. In this case, the applicant shall pay only the state duty established for the registration.

(point 12 edited by No 1873-N of 28 November 2024)

13. In the first stage of the expert-examination, a preliminary study of the documents and materials submitted by the applicant shall be carried out, including verifying the integrity, completeness and accuracy of drawing up of the package of documents, the results whereof (including incomplete or missing documents and

materials) shall be notified to the applicant in writing.

14. In case of failure to submit the required materials and documents within 60 calendar days following the notification of the results of the first stage of the expert-examination, the request shall be rejected on the grounds that the submitted documents and (or) materials are incomplete. The specified period shall not be included in the total period for conducting the expert-examination.

15. During the expert-examination, the applicant cannot make changes to the submitted documents on his/her own initiative.

16. In the second stage of the expert-examination, in case of a substantiated written requirement by the Organisation to assess the efficiency, safety and quality of the medicines, the applicant shall submit — during the expert-examination — additional materials and data, make changes and supplements to the notes on the primary and (or) outer packaging of the medicine, the general description of the medicine (instruction for medical use), the instruction for use (leaflet) and (or) specifications or the normative document of quality. Subsequent inquiries to the first requirement shall be permitted only when clarification is needed regarding the materials sent in response to the previous one.

(point 16 supplemented by No 1873-N of 28 November 2024)

17. The maximum term for submitting responses shall be 120 calendar days. In case of failure to submit additional or missing materials required at the expert-examination following the expiry of 120 calendar days from the day the need for submission thereof has been duly notified of, the expert-examination shall be terminated, and an expert-examination opinion regarding the rejection of the registration shall be drawn up.

18. In case of general procedure, the expert reports on quality, pre-clinical testing, clinical trials and accompanying information, the conclusion of the laboratory examination and the report of professional monitoring (if any) shall serve as a

basis for the expert opinion.

19. In case of simplified procedure, the opinion of a comparative expert-examination of the data on the composition, specifications or the normative document of quality, manufacturing sites, research data and accompanying information of the medicine approved by the referring competent authority and the medicine registered in the Republic of Armenia, shall serve as a basis for the expert opinion, which shall be signed by the expert.

(point 19 supplemented by No 1873-N of 28 November 2024)

20. Where it turns out during the expert-examination that the amount of the state duty paid for the expert-examination does not correspond to the amounts defined, the underpaid state duty shall be subject to payment within a period of 5 days upon the day of the receipt of the notification thereof.

(point 20 edited by No 1873-N of 28 November 2024)

21. Regardless of the outcome of the expert-examination, the documents, materials submitted for the expert-examination for the purpose of registration and the state duty shall not be returned, ensuring the permanent preservation and record-registration of the documents in the Organisation, except for cases where the expert-examination has not started or the state duty has been paid in excess of the established amount.

(point 21 amended, supplemented by No 1873-N of 28 November 2024)

22. Prior to submitting the request, upon the wish of the applicant, the Organisation may —for the purpose of clarification of data submission – provide paid consultation on the selection of procedures for registration, the volume of documents from the perspective of ensuring the integrity of packages corresponding to different types of requests of registration.

2. EXPERT-EXAMINATION FOR THE PURPOSE OF REGISTRATION

23. Materials submitted during the expert-examination for the purpose of registration shall be subject to expert-examination, assessing the quality, safety, efficiency, risk-benefit ratio, and reliability of information.

24. The maximum duration of expert-examination through general procedure shall be 140 calendar days.

25. During the expert-examination through general procedure, the compliance of the data on quality, safety, and efficiency with the requirements of guidelines of the ICH and (or) the WHO shall be verified.

26. The quality of medicines, the active ingredients and excipients thereof, the container and sealing materials must comply with the requirements of the European Pharmacopoeia. In case of absence of relevant articles in the European Pharmacopoeia, the quality thereof must comply with the requirements of the European Union Member State or the Eurasian Economic Union or the Member State or the British Pharmacopoeia or the United States Pharmacopoeia or the International Pharmacopoeia or the Japanese Pharmacopoeia, and the quality of homeopathic medicines must comply with the requirements of the German Homeopathic Pharmacopoeia.

27. Reports of pre-clinical testing and (or) clinical trials shall be required for the registration of new combinations of medicines or medicines reproduced in a new dosage or new pharmaceutical form or under a new indication, different from the original.

28. Pre-clinical testing of the registered medicine must be conducted in accordance with the rules of good laboratory practice approved by the Authorised Body, and clinical trials must be conducted in accordance with the rules of good clinical practice approved by the Authorised Body. The production of medicines, medical substances and researched pharmaceutical products (in all manufacturing sites involved in the manufacturing process) must comply with the rules of good

manufacturing practice approved by the Authorised Body, and herbal raw materials must comply with the rules for the proper processing and collection of herbal raw materials approved by the Authorised Body.

29. During the registration of a reproduced medicine, the applicant shall not be required to submit data on pre-clinical testing and (or) clinical trials in case the applicant submits documents which demonstrate that the medicine is reproduced from the original medicine that was registered in the Republic of Armenia or in the member country of the ICH for not less than eight years. In this case, the request for registration of the reproduced medicine shall be accepted, and the expert-examination shall be conducted, but the medicine may be circulated after ten years following the registration of the original medicine. Where the holder of the certificate of registration registers one or more new indications within a ten-year period, the term shall be extended for another one year at large.

30. Studies of biological medicines must comply with the requirements of the documents adopted by the ICH and (or) the WHO guidelines.

31. Bioequivalence studies of reproduced medicines must be conducted in accordance with the WHO guidelines and (or) requirements of the ICH member country. The applicant shall not submit data on bioequivalence studies for the reproduced medicine where the documents submitted thereby prove that that medicine was used in the Republic of Armenia or in the member country of the ICH for more than ten years. In such cases the applicant shall submit only relevant data on the academic literature.

32. In case of compliance of quality criteria (specifications or the normative document of quality) with the pharmacopoeias in force in the Republic of Armenia, the laboratory expert-examination of the quality of submitted samples shall start to verify the compliance of quality with the specifications or the normative document of quality and the reproducibility of the described methods.

A protocol shall be drawn up regarding the laboratory expert-examination.

(point 32 supplemented by No 1873-N of 28 November 2024)

33. Depending on the request, expert reports shall be drawn up on the results of pre-clinical testing, clinical trials, and quality assessment.

34. For the purpose of assessing the compliance of the documents submitted during the expert-examination, the product or manufacturing process, a pre-registration professional monitoring may be conducted in accordance with Annex No 5 to this Decision. Monitoring shall be conducted within the period specified for the expert-examination.

35. In case of simplified procedure, the maximum duration of expert-examination shall be 21 calendar days.

36. In case of the simplified procedure, the report on the expert-examination conducted by the Reference Competent Authority for medicines registered in an ICH member state or prequalified by the WHO shall be evaluated by comparing it with the submitted documents and data.

37. In case of the simplified procedure, where there is inconsistency of qualitative and quantitative composition, manufacturing site, stability and data of specifications or the normative document of quality, as well as accompanying information, the applicant shall be notified, and in case of his/her consent, after making the necessary payments, registration shall be carried out through the general procedure approved by this Decision.

(point 37 supplemented by No 1873-N of 28 November 2024)

38. During the expert-examination for the purpose of registration through general and simplified procedures, the compliance of the primary and (or) outer packaging, the general description of the medicine (instruction for medical use), and the instruction for use (leaflet) with the requirements established by the

legislation of the Republic of Armenia shall also be verified, while simultaneously developing the Armenian version of the instruction for medical use (general description of the medicine) and the instruction for use (leaflet). In case of heavy workload, the development of Armenian versions may be carried out after registration, within a maximum of 180 days, ensuring the approval and publicity of the document in the original language before that.

(point 38 amended, supplemented by No 1873-N of 28 November 2024)

39. Where during the expert-examination it becomes clear that the name of the medicine is the same or confusingly similar to the name of an already registered medicine containing other medical substances, the applicant shall be recommended to change the name, and in case of failure to change the name, a conclusion on refusing the registration shall be drawn up.

40. Based on part 24 of Article 16 of the Law of the Republic of Armenia "On medicine", the fact of whether or not the medicine falls under the groups of medicines sold on prescription or with no prescription, in accordance with the legislation of the Republic of Armenia, shall also be determined during the expert-examination.

41. The results of the expert-examination shall be summarised in the Organisation, and an expert opinion shall be drawn up, in accordance with the form attached, attaching the drawings of the primary and (or) outer packaging of the medicine, the general description of the medicine (instruction for medical use), the instruction for use in Armenian (leaflet), the quality specification or the normative document of quality and the agreed risk management plan (if available).

(point 41 supplemented by No 1873-N of 28 November 2024)

42. The holder of the certificate of registration shall — prior to the import of the medicine and (or) at the time of the first import —submit to the Organisation one sample of each of the primary and (or) outer packaging, from the final

printed copies.

43. The Organisation shall notify the applicant in writing on the working day following the end of the expert-examination about the results of the expert-examination and the necessity and amount of payment of the state duty.

(point 43 supplemented by No 1873-N of 28 November 2024)

3. EXPERT-EXAMINATION FOR THE PURPOSE OF RE-REGISTRATION

44. During the expert-examination for the purpose of re-registration, reassessment of the quality, safety, efficiency, and benefit-harm ratio of the medicine shall be conducted, based on the results of post-registration monitoring.

45. The maximum duration of the expert-examination shall be 110 calendar days, which shall include also the period for the expert-examination of post-registration modifications, where necessary. During the expert-examination, after the expiry of the validity period of the previous certificate, data on the medicine shall be stored in the register, making a note, indicating that a request for re-registration has been submitted.

(point 45 edited by No 1873-N of 28 November 2024)

46. The re-registration shall be rejected in case of availability of the grounds prescribed by part 27 of Article 16 of the Law of the Republic of Armenia "On medicine".

47. The expert opinion shall be submitted to the Authorised Body as prescribed by Annex No 1 approved by this Decision.

4. EXPERT-EXAMINATION FOR THE PURPOSE OF EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE

48. During the expert-examination for the purpose of extending the validity period of the certificate, data on the safety of the medicine, obtained during the post-registration period, shall be evaluated. Where during the expert-examination it becomes clear that it is necessary to make post-registration modifications, after sending a notification to the applicant, the process shall be terminated before the submission of relevant documents thereon and the completion of the expert-examination.

(point 48 supplemented by No 1873-N of 28 November 2024)

49. The maximum duration of expert-examination shall be 20 calendar days. During the expert-examination, after the expiry of the validity period of the previous certificate, data on the medicine shall be stored in the register, making a note indicating that an application for extending the validity period of the certificate has been submitted.

(point 49 edited by No 1873-N of 28 November 2024)

50. The expert opinion shall be submitted to the Authorised Body as prescribed by Annex No 1 approved by this Decision.

51. The extension of the validity period of the certificate shall be rejected in case of availability of the grounds prescribed by part 27 of Article 16 of the Law of the Republic of Armenia "On medicine".

5. PRESENTING POST-REGISTRATION MODIFICATIONS AND EXPERT-EXAMINATION THEREOF

52. All the modifications made following the registration shall be subject to expert-examination.

53. The expert-examination shall be carried out within 30-90 calendar days, depending on the type of the modification, as per the impact on the quality,

safety and efficiency (first, the impact is minimal and (or) is missing, second, the impact is significant).

54. Modifications related to the quality, safety and efficiency of a medicine registered through the simplified procedure must be approved by the Reference Competent Authority.

55. The results of the expert-examination shall be summarised in an expert opinion.

56. The expert opinion shall be submitted to the Authorised Body on the working day following the completion of the expert-examination.

57. The post-registration modifications shall be rejected in case of availability of the grounds prescribed by part 27 of Article 16 of the Law of the Republic of Armenia "On medicine".

58. The Authorised Body shall issue an order on accepting or rejecting post-registration modifications of the medicine within 3 working days upon receipt of the expert-examination opinion.

59. Within 2 working days from the moment the order of the Minister is adopted, it shall be sent to the applicant via e-mail and (or) postal delivery.

60. Where the modifications are accepted, the register shall be revised, indicating the type of the modification and the dates of acceptance.

61. The Organisation shall — on the working day following the completion of the expert-examination — notify the applicant in writing of the results of the expert-examination, informing about the modifications that require new registration (if available).

62. The modifications listed in Annex No 4 to this Decision shall be attached to the package of registration documents, in accordance with the order of the Minister, by reformulating the certificate, in accordance with the procedure approved by the Authorised Body.

63. The reformulated certificate shall be issued to the applicant within 5 working days from the moment of entry into force of the order of the Authorised Body on approving the modifications.

64. In case of modifications related to the design (color design) of the bar code and instructions for use, as well as those that do not relate to the quality, efficiency and safety, the previously approved packages of the medicine shall remain in force for medicines manufactured within 180 calendar days following the adoption of the new modifications as well.

(point 64 supplemented by No 1873-N of 28 November 2024)

65. Within a maximum of one month after the expert opinion on post-registration modifications is drawn up, supplement to the reports on the expert-examination for registration of medicine and expert opinion shall also be made, taking into account the new information.

Prime Minister
of the Republic of Armenia N. Pashinyan

Form

EXPERT OPINION ON SAFETY, EFFICIENCY AND QUALITY ASSESSMENT

Name of the product _____

Dosage _____

Pharmaceutical form _____

Composition, indicating the international non-patented name, the quantity(ies) of the active ingredient(s)_____

Packaging, release form _____

Product type (for human use, veterinary, homeopathic, immunological, herbal, radioactive, etc.) _____

Issuance order (on prescription, over-the-counter, controlled) _____

Manufacturers involved in the manufacturing process, including the manufacturer of dosage, bulk manufacturer, packager, final product manufacturer, quality supervisor, batch releaser (name, address, country) _____

_____

_____

Holder of the certificate of registration (name, address, country) _____

Anatomical-therapeutic-chemical (ATC) code _____

Instructions for use _____

Expiry date _____

Storage conditions _____

Registration case _____

Registration procedure (simplified, general, re-registration, etc.) _____

_____

Registration (rejection) data in other countries _____

Results of expert-examination for quality _____

Results of the expert-examination for efficiency and safety _____

Conclusion _____

Day, month, year _____

Signature _____

(Annex amended, supplemented, edited by No 1873-N of 28 November 2024)

Annex No 3

to Decision of the Government
of the Republic of Armenia
No 162-N of 28 February 2019

LIST

OF DOCUMENTS REQUIRED FOR EXPERT-EXAMINATION CONDUCTED FOR THE PURPOSE OF STATE REGISTRATION, RE-REGISTRATION OF MEDICINE, EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE, AS WELL AS FOR SUBMITTING POST-REGISTRATION MODIFICATIONS AND EXPERT-EXAMINATION

1. DOCUMENTS REQUIRED FOR REGISTRATION OF MEDICINE

1. Request with information on the case of registration and the medicine;
2. Package of documents, in accordance with the common technical document of the ICH;
3. The expert-examination report conducted by the competent authority of another country or during the pre-qualification of the WTO and the original copy of the approved specifications or the normative document of quality and instructions for use, constituting a part thereof, and translated versions thereof, where they are not in Russian or in English (mandatory in case of the simplified procedure).

   (point 3 supplemented by No 1873-N of 28 November 2024)
4. The document certifying the fact of payment of the state duty established for the expert- examination.

   (point 4 edited by No 1873-N of 28 November 2024)

2. DOCUMENTS REQUIRED FOR RE-REGISTRATION OF MEDICINE

1. Request with information on the case of re-registration and the medicine;

2. Module 1 of the package, in accordance with the ICH common technical document;

3. Side effect monitoring report in a format approved by the Authorised Body;

4. The document certifying the fact of payment of the state duty established for the expert- examination.

(point 4 edited by No 1873-N of 28 November 2024)

3. DOCUMENTS REQUIRED FOR EXTENDING THE VALIDITY PERIOD OF THE CERTIFICATE

1. Application;

2. The document certifying the fact of payment of the state duty established for the expert- examination.

(point 2 edited by No 1873-N of 28 November 2024)

4. DOCUMENTS REQUIRED DURING THE SUBMISSION OF POST-REGISTRATION MODIFICATIONS

1. Request describing the type of the modification(s), in accordance with Annex No 19 to Decision of the Council of the Eurasian Economic Commission No 78 of 3 November 2016;

(point 1 supplemented by No 1873-N of 28 November 2024)

2. Documents regarding the change(s), including relevant substantiations and (or) clarifications;

3. The document certifying the fact of payment of the state duty established for the expert- examination.

(point 3 edited by No 1873-N of 28 November 2024)

(Annex supplemented, edited by No 1873-N of 28 November 2024)

Prime Minister
of the Republic of Armenia N. Pashinyan

Annex No 4

to Decision of the Government
of the Republic of Armenia
No 162-N of 28 February 2019

LIST

OF MODIFICATIONS CONCERNING THE REGISTERED MEDICINES,
WHERE NO NEW REGISTRATION IS REQUIRED

1. Based on the requirement of part 20 of Article 16 of the Law of the Republic of Armenia "On medicine", the list of modifications concerning the registered medicines, where no new registration is required and the certificate of registration of the medicine is re-issued, shall be established by this Annex.

2. The modifications concerning the registered medicines, where no new registration is required, shall be the following:

(1) change in the name and (or) location of the holder of the certificate of registration, where the legal entity has remained unchanged;

(2) change only in the name of the medicine, without any other modifications;

(3) modification in the non-patented name without change in the medical

substance;

(4) change in the manufacturer's name without changing the manufacturer and the location thereof;

(5) modification in the form of release, which is associated with quantitative changes in the units included in the package.

Prime Minister

of the Republic of Armenia N. Pashinyan

Annex No 5

to Decision of the Government

of the Republic of Armenia

No 162-N of 28 February 2019

PROCEDURE

FOR RECOGNITION OF PROFESSIONAL MONITORING AND MONITORING REPORTS OF COMPETENT AUTHORITIES OF OTHER COUNTRIES

1. This Procedure shall regulate the relations related to conducting professional monitoring during the state registration of medicines in the Republic of Armenia and the recognition of monitoring reports conducted by competent authorities of other countries.

2. Professional monitoring or recognition of monitoring reports of competent authorities of other countries shall be conducted by an expert organisation (hereinafter referred to as "the Organisation") established by a decision of the Government of the Republic of Armenia.

3. All the experts of the organisation conducting monitoring shall be obliged to sign

a declaration of conflict of interests and confidentiality in the form prescribed by the Authorised Body.

4. The expenses with respect to professional monitoring shall be compensated by the applicant, based on the agreement concluded between the parties as prescribed by law.

5. The professional monitoring shall be conducted instantly on the manufacturing site, as well as in the venues of pre-clinical testing, clinical trials and bioequivalence studies (including those carrying out activities on a contractual basis).

6. Professional monitoring shall be conducted for the expert-examination of registration of medicines within the terms established by the Law of the Republic of Armenia "On medicine", based on the expert reports on the results of the documentary expert-examination.

7. Based on the results of the risk assessment, in non-high-risk cases, professional monitoring may be conducted within a maximum of three years after registration.

(point 7 amended by No 1873-N of 28 November 2024)

8. For the purpose of regular risk-benefit evaluation, data relevant to the registration of relevant medicine or related thereto may be required during the monitoring.

9. The assessment of compliance of Good Manufacturing Practice (GMP) in the manufacturing site shall be carried out through the procedure approved by the Government of the Republic of Armenia, in accordance with the Law of the Republic of Armenia "On medicine".

10. Monitoring at the sites of pre-clinical testing, clinical trials and bioequivalence studies shall be conducted within 30 calendar days after informing the applicant.

The maximum term for monitoring shall be 5 working days. Based on the results of the monitoring, a protocol shall be drawn up, which shall be signed by the expert(s) conducting the monitoring and the representative of the applicant.

11. In case of positive results of monitoring of GMP compliance conducted by competent authorities of states that are members to the Pharmaceutical Inspection Co-operation Scheme and the Eurasian Economic Union within the previous three years, the reports shall be recognised, and no monitoring is conducted, except for cases when inconsistencies have been identified as a result of the expert-examination, the study whereof requires conducting professional monitoring during registration or after registration, in accordance with this Procedure.

(point 11 supplemented by No 1873-N of 28 November 2024)

12. In case of positive results of observations conducted during the prequalification by the WHO, as well as that conducted by competent authorities of states that are members to the ICH and Eurasian Economic Union at the sites of pre-clinical testing, clinical trials and bioequivalence studies, the reports shall be recognised, and no monitoring is conducted, except for cases when inconsistencies have been identified as a result of the expert-examination, the study whereof requires conducting professional monitoring during registration or after registration, in accordance with this Procedure.

(point 12 supplemented by No 1873-N of 28 November 2024)

(Annex amended, supplemented by No 1873-N of 28 November 2024)

Prime Minister

of the Republic of Armenia N. Pashinyan